EXHIBIT I

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Hand augmentation with Radiesse® (Calcium hydroxylapatite)

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ABSTRACT: The hand has remained a considerable treatment challenge, as new soft tissue fillers have arrived in the esthetic marketplace. The challenge has been the result of both the multiple visits required for treatment in, for example, autologous fat grafting and the simple management of pain in the innervated areas of the hand between the bones.

This paper introduces a novel, noticeably less painful approach to treatment of the hand with calcium hydroxylapatite (CaHA; Radiesse®, BioForm Medical, San Mateo, CA). Anesthetic is added to the compound prior to injection, resulting in a homogenous admixture of CaHA and anesthetic. A bolus of the mixture is injected into the skin, using tenting, and then spread throughout the hand.

The result of this approach – mixing anesthetic with CaHA – is treatment that is easier to massage and disseminate, less painful to the patient than conventional hand injection, and characterized by less swelling and bruising, with minimal post-treatment downtime.

KEYWORDS: calcium hydroxylapatite, hand augmentation, Radiesse®

Introduction

Hand augmentation is part of the armamentarium of hand rejuvenation. In both men and women, volume restoration in the hands can provide a plumper, more youthful appearance, reduce skin laxity and wrinkling, and reduce the prominence of underlying structures such as bones, tendons, and veins (1).

The ideal filler for this purpose effectively adds bulk and volume and is durable enough to withstand repeated dynamic motion. Autologous fat grafting is one strategy for volume restoration.

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However, it may require several visits and injections, and necessitates the removal of fatty tissue from another site on the body (donor site). Furthermore, results of autologous fat grafting may not be predictable.

Other soft tissue fillers are also increasingly employed for augmentation of the hands (2). One such filler is calcium hydroxlapatite (CaHA; Radiesse®). This communication presents a novel technique that optimizes the use of CaHA for hand augmentation. Although CaHA is approved for facial esthetic use in the United States, its offlabel use for hand augmentation has not been reported in the literature until now.

Technique

Combining the soft tissue filler with the anesthetic

To begin, 0.1 mL of plain 2% lidocaine is introduced into the 1.3 mL syringe of Radiesse® through a

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Rapid Fill™ Luer-Lok-to-Luer-Lok connector (Baxa; Englewood, CO) and a 1 mL syringe with Luer-Lok. To avoid clogging, introduce Radiesse® into the syringe containing anesthetic first. Then push the newly combined Radiesse® and 2% lidocaine back and forth from syringe to syringe until it becomes a homogeneous mixture (FIG. 1).

Identifying the area of treatment

The space that is injected is bound laterally by the fifth metacarpal, medially by the second metacarpal, proximally by the dorsal wrist crease, and distally by the metacarpophalangeal joints. Approximately 1.3 mL of Radiesse fills this subcutaneous space of the dorsum of the one hand (FIG. 2a).

Isolating the area of treatment

Skin tenting is used to separate skin from vascular and tendinous structures by using the thumb and forefinger of the noninjecting hand to lift skin

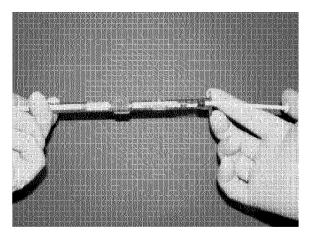


FIG. 1. Mixing anesthesia with CaHA.

over the dorsal aspect of the hand being treated, as shown in FIG. 2a.

Injecting the mixture into the hand

Filler mixture is introduced as a bolus (0.5–1.4 mL) in the areolar plane between the subcutaneous layer and superficial fascia (FIG. 2b).

Immediately after injection, the injection site should be gently massaged (FIG. 2c) until the filler has been evenly spread. To allow for more even distribution, the patient should make a fist of the newly injected hand as the physician manipulates the injected area.

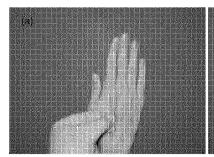
Before and after results of the injection of the combined mixture of anesthetic and Radiesse® are shown in FIG. 3.

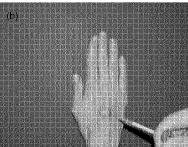
Adverse events, postinjection procedures and follow up

In general, no massage by the patient is required or encouraged. Patients may experience some temporary swelling; bruising should be minimal to nonexistent. Patients can resume their activities of daily living the next day. A follow-up office visit in 2 weeks provides an opportunity to express any concerns about the treatment and discuss other problems the patient may be having.

Conclusion

This report demonstrates a method to introduce anesthetic into a soft tissue filler that appears to alter its physical characteristics such as extrusion force and viscosity. The mixing technique described here renders the filler less cohesive and provides a smoother flow during injection. The product is easier to massage and disseminate, and is thus considerably less painful to the patient than conventional





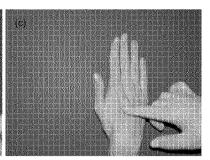


FIG. 2. Injection technique. This figure shows the tenting technique (FIG. 2a) when injecting a bolus of filler into the dorsal aspect of the hand (FIG. 2b). A massage of the treated area should follow injection of the bolus (FIG. 2c).

FIG. 3. Patient before and after hand augmentation. Figure 3 shows a 38-year-old patient before (3a) and immediately after injection of 1.3 mL of CaHA for augmentation of the hands (3b).

injection into the area of the hand. In addition, the technique for hand augmentation allows entry from a single entry site, thus decreasing the chance for bruising and swelling. Minimal to no downtime along with no post-treatment restrictions have made this a relatively simple procedure to help volumize the dorsum of the hand.

References

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